

REJECTIONS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 1-26 and 35 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner contends that the claims are indefinite due to the recitation of the phrases "isolating sperm from said selected sperm sample to produce isolated sperm" and "final extender". Applicant traverses this rejection for the reasons set forth below.

One of skill in the art would know that sperm cells no longer in the testicles are not "isolated" but accompanied by seminal fluid, proteins etc. Thus, Applicant submit that one of skill in the art would understand the recitation "isolating sperm from said selected sperm sample to produce isolated sperm". Accordingly, withdrawal of this rejection is respectfully requested. Likewise the phrase "final extender" is defined in the specification at page 4, lines 20-21. Thus, one of skill in the art will understand the recitation "final extender." Withdrawal of this ground of rejection is also respectfully requested.

REJECTIONS UNDER 35 U.S.C. § 103(a)

Claims 1-26 and 35 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Salisbury et al. taken with Spaulding (U.S. Patent No. 5,012,244). Applicant respectfully traverses this rejection for the reasons set forth below.

The instantly claimed invention is directed to a method for freezing sperm selected for a particular characteristic (e.g., sex selected) which, when the sperm is thawed results in viable sperm that can be used in procedures such as artificial insemination ("AI") and in vitro fertilization ("IVF"). The method facilitates the storage and/or shipment of selected sperm samples to sites distant from the collection site and represents an important advance in livestock management, where selection of sperm for use in such procedures can be used to increase the production of offspring having desirable traits (see specification, page 3, lines 9-24).

Prior researchers had demonstrated that the stresses associated with various selection methods or with cryopreservation resulted in significant losses in fertility and/or viability of sperm. The selection and subsequent processing of sperm presents unique challenges because sperm is relatively susceptible to physical injury, are incapable of DNA repair and exhibit

decreased fertility with increasing time between collection and use. As most of the available selection methods involve physical stresses and take time, selected sperm are compromised compared to non-selected sperm. Fertility is generally further reduced if the selection technique (e.g., flow cytometry) involves significant dilution (see specification, page 1, lines 28-31, page 2, lines 1-5). In addition, the freezing of sperm invariably reduces fertility, motility, and/or viability (see specification, page 2, lines 15-17). Although techniques for freezing unselected sperm are known, *no technique for repeatedly producing viable cryopreserved selected sperm has been described prior to the instant disclosure.*

Moreover, prior to applicant's invention, no viable pregnancies had been achieved or no offspring exhibiting the selected characteristic had been produced using selected cryopreserved sperm. Thus, for one of ordinary skill in the art, there would be no reasonable expectation of success in using cryopreserved selected sperm to produce pregnancies which resulted in offspring with the selected characteristic. *The present inventors have demonstrated, for the first time, that pregnancies can be achieved with sperm that have been selected and then frozen and that the resulting offspring exhibit the selected characteristic.*

Releas *Claim 5*
Salisbury *Claim 6*
discusses extenders and the extension of unfrozen semen and some techniques for freezing
unselected sperm. *Salisbury does not teach or suggest that sperm selected for a particular*
characteristic may be frozen or that pregnancies can be achieved with such selected
cryopreserved sperm. *Such a disclosure is found only in the instant application.* *Thus, Salisbury*
cannot render the claimed invention obvious.

Spaulding *Claim 7*
relates to a method for sex selecting sperm utilizing sex associated membrane
antibodies. *Spaulding does not teach or suggest that sperm selected for a particular characteristic*
may be frozen and that pregnancies can be achieved with such selected cryopreserved sperm.
Accordingly, Spaulding does not remedy the deficiency of Salisbury. *Thus Spaulding, either*
alone or in combination can not render the claimed invention obvious.

Applicant respectfully submits that a proper analysis under 35 USC § 103 requires a
consideration of two factors: (1) whether the prior art would have suggested to those of ordinary
skill in the art that they should make the claimed composition or device, or carry out the claimed
process; and (2) whether the prior art would also have revealed that in so making or carrying out
, those of ordinary skill would have a reasonable expectation of success. *Both the suggestion and*

the reasonable expectation of success must be found in the prior art, not applicant's disclosure. In re Vaeck 947 Fed, 2d 488, 493, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). The cryopreservation of selected sperm and the use of such sperm to achieve viable pregnancies which result in offspring with the selected characteristic is found only in the instant application, and not in the cited references. Thus the cited references cannot render the claimed invention obvious. Accordingly, applicant respectfully requests withdrawal of this ground of rejection.

The Examiner also contends that while "the steps of the process of Salisbury might be out of order from the claimed process" the invention is still obvious because "it is *prima facie* obvious to perform in any order steps of a process" (MPEP 2144.04 IV (C)). Applicant respectfully traverse this rejection for the reasons discussed below.

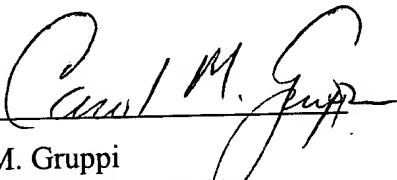
There is no basis in the law for treating combinations of old elements differently in determining patentability. Fromson v Advance Offset Plate, Inc. 755 F.2d 1549, 225 USPQ 26 (Fed. Cir. 1985). Thus, whether the combination of elements is old or new, an analysis under 35 USC § 103 requires consideration of the two factors discussed herein above. As also discussed above, to one of ordinary skill in the art, there would be no reasonable expectation of success in using cryopreserved selected sperm to produce pregnancies which resulted in offspring with the selected characteristic. Accordingly, the claimed invention is not rendered obvious and withdrawal of this ground of rejection is respectfully requested.

CONCLUSION

Applicants respectfully submit that the claims comply with 35 U.S.C. § 112, second paragraph and define an invention that is patentable over the art. Accordingly, allowance is in order, and an early notification to that effect would be appreciated. Should the Examiner in reviewing the communication have any questions or need any additional information, he is welcome to contact the undersigned at (650) 849-4902.

A fee of \$445.00 is due under 37 C.F.R. § 1.16 and § 1.17 for the Petition for a an Extension of Time filed concurrently herewith. The Assistant Commissioner is hereby authorized to charge any additional fees which may be required by this paper, or credit any overpayment to Deposit Account No. 50-1189. Docket No.: 22091-701CON1.

Respectfully submitted,

By: 
Carol M. Gruppi
Registration No.: 37,341

Dated: June 19, 2001

Mailing Address:

McCutchen, Doyle, Brown & Enersen, LLP
Three Embarcadero Center
San Francisco, California 94111
Telephone: (650) 849-4400
Telefax: (650) 849-4800